PACIFIC ECORISK | ENVIRONMENTAL CONSULTING & TESTING

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December 4, 2009

Dear Danny,

Pacific EcoRisk (PER) is pleased to have the opportunity to provide you with comments on the draft document entitled *Diuron Criteria Derivation (Fojut et al., 2009)*. We would like to acknowledge that the task that the authors have undertaken in preparing this document, as there was clearly a significant effort made to review a relatively large number of scientific articles. However, we have some comments that we believe are critical for the development of sound and scientifically defensible water quality criteria.

Diuron Criteria Derivation Report: General Comment

An updated methodology for deriving freshwater quality criteria for the protection of aquatic life was developed (TenBrook *et al.,* 2009) and was used for the derivation of criteria for the protection of aquatic life for the herbicide diuron.

PER Comment 1:
Although the public comment window for the "Phase II" Report (TenBrook et al., 2009) method has passed, we are compelled to express that this method (and others) lack an effective "kill switch" to outright reject critically flawed studies for use in deriving water quality criteria. There are two critical elements that Pacific EcoRisk believes should be part of any credible scientific publication that is used for criteria derivations:

- Measured (i.e., verified analytically) concentrations of the chemical being tested; and
- A valid control response (i.e., a minimally acceptable level of test response such as 90% survival in an acute test) for the given test method.

Studies that only report "nominal" test concentrations should not be used for criteria derivation. There is simply no assurance that the concentrations that are reported in such literature sources are the **actual** concentrations for the exposures, particularly for older studies in which the ancillary QA measures that are standard for modern studies were not performed. Errors in solution preparation, accuracy of the analytical equipment/instrumentation (e.g., balances, pipettes, etc.), chemical stability, chemical solubility, etc., can potentially result in significant differences between the nominal concentration and the actual concentration of the exposure. Furthermore, the statistical analysis of the test data should be performed using the actual measured concentrations to be accurate. Without such assurance of accuracy, the applicability of such test results for criteria derivation is questionable and could result in incorrect criteria (e.g., both under protective or over protective).

The Phase II Report rating system allows the use of a study that is complete in all aspects except that the Control treatment "failed", since this would result in a score of 92.5 out of 100 for the study. Under most regulatory applications (e.g., CVRWQCB NPDES permits), and for most aquatic toxicity test methods (e.g., EPA aquatic toxicity test methods), a failed Control treatment response invalidates the test, with a concomitant requirement to repeat the test. It is inconsistent for one regulatory program (e.g., NPDES) to invalidate data based on a failed Control treatment response, but for another regulatory framework (e.g., the Basin Plan amendment process) to accept literature-derived test results with a failed Control treatment response for use in deriving water quality criteria.

Although the above comments relate primarily to the method established in "Phase II" Report (TenBrook et al., 2009), the absence of "kill switches" in the method has allowed the use of questionable? data in the Diuron Criteria Derivation.

Diuron Criteria Derivation Report: Ecotoxicology Data – Evaluation of Aquatic Plant Data

In the Phase II Report protocol, full "points" would be given to plant studies for which key water quality parameters were reported. However, in the Diuron criteria derivation, test data from studies without such critical water quality data were used without any qualification (Page 5 of the Diuron report indicates that "the test parameters of dissolved oxygen, hardness, alkalinity, and conductivity were not considered in the evaluation of reliability as they are not relevant in plant studies."

PER Comment 2:
Unilateral selection of some but not all of the scoring methods in the Phase II Report is inappropriate. As per Section 14.10.2.3.1 of Method 1003.0 (the green alga, Selenastrum capricornutum, growth test, EPA 821-R-02-013): "Alkalinity, hardness, and conductivity are measured at the beginning of the test in the high, medium, and low concentrations and control before they are dispensed to the test chambers…" Clearly, EPA scientists have deemed that these parameters are an essential component of the Selenastrum method. Awarding full points to studies for which essential water quality data (e.g., alkalinity, hardness, and conductivity) are not available is not only unacceptable by the EPA method, but it also creates an undesireable slippery slope of selective adherence of the Phase II protocol for this criteria derivation and for future criteria derivations.

The Diuron Criteria Derivation should be revised to award properly diminished points to the studies that lack critical support data.

Diuron Criteria Derivation Report: Acute Criterion Calculation

Consistent with the Phase II Report protocol, for a data set with insufficient data to apply a species sensitivity distribution (SSD), an "acute value" is obtained by dividing the lowest species mean acute value by an assessment factor (AF). This value is then divided by a safety factor of 2 to obtain a preliminary acute criterion to approximate a no effect level.

Following this process, the authors obtained a preliminary acute criterion of 168 µg/L. However, the authors of the criteria derivation then chose to implement a second application of the safety factor to arrive at a final criterion of 84 µg/L based on the consideration that:

1. **limited data were available for the acute criterion calculation,**
2. **that the assessment factor (AF) may be of limited use for herbicides, and**
3. **in order to be protective of all species in the supplemental data set.**

The authors of the derivation attempt to justify this arbitrary second application of the safety factor by observing that the resultant value is coincidentally similar to the 80 µg/L that results from the EPA's application of the safety factor to the LC50 of 160 µg/L for *Gammarus lacustris* (Sanders 1969).

PER Comment 3:
The derivation authors' unilateral decision to deviate from the Phase II Report protocol in implementing a second application of a safety factor is unwarranted and inappropriate without justification that is consistent with the Phase II Report protocol. If this approach is allowed to move forward, a precedent is being established by which the authors of any other future pesticide criteria derivations may elect to deviate from the Phase II protocol at will and without justification.

PER Comment 4:
The authors of the derivation acknowledge that the Sanders 1969 paper was rated "Less reliable-Less reliable" (LL), and that Sanders did not report the test response for the Control treatment of their test. As per our Comment #1 about the need for "kill switches" for data evaluations, we suggest that this paper should be rejected for use in criteria derivation since it is critically flawed. This paper should by no means be used to justify the application of an additional safety factor.

Diuron Criteria Derivation Report: Chronic Criterion Calculation

All papers that were deemed acceptable for use in the chronic criterion calculation only reported nominal chemical concentrations.

PER Comment 5:
As per PER Comment 1 above, papers without measured pesticide concentrations are severely flawed and should not be used for criteria derivation. As this would result in the rejection of all of the literature-reported data that the authors used in their derivation (reported in Table 7a), we suggest the following:

1. The current derivation effort identify that there are no acceptable chronic data and that a chronic criterion can not be established at this time;
2. That in the absence of appropriate data, a chronic criterion be established but that it be identified as an "Interim Chronic Criterion" to be used until such time as appropriate data become available;

3. That scientifically sound studies should be performed to support the chronic criteria derivation rather than using flawed studies to simply obtain a number.

Diuron Criteria Derivation Report: Chronic Criterion Calculation

The derivation authors indicate that the Phase II Report protocol requires that in the absence of acceptable data to fit a species sensitivity distribution (SSD), that the lowest No Observed Effect Concentration (NOEC) value from an important alga or vascular aquatic plant species be used. The authors further state in the Final Criteria Statement section of their report that "the use of the NOEC value as the chronic criterion is recommended in order to be protective of nonvascular plants".

PER Comment 6:
The NOEC is a measure of toxicity that is often used for regulatory purposes (i.e., calculation of Toxic Units [TU], where TU = 100/NOEC). Determination of the NOEC is based upon statistical comparisons of test treatments with a Control treatment to determine if there is a statistically significant reduction at the test treatment relative to the Control. Recognized problems with the use of the NOEC as a regulatory benchmark or for use in the derivation of water quality criteria include:

1. The typical toxicity test consists of the evaluation of 5 or 6 specific chemical concentrations that are generally arbitrarily decided upon (e.g., the a priori decision to use 5 ug/L, 10 ug/L, 25 ug/L, 50 ug/L, and 100 ug/L of the chemical in question as the test treatments). As a result, and by definition, the NOEC will almost never accurately identify the actual chemical concentration at which there is "no effect", but rather will be limited to the identification of the highest test treatment at which there is no effect. For instance, in the example test concentrations described above, it would be possible to have a slight but statistically significant effect at the 100 ug/L concentration for a chemical that would have no significant effect at the 90 ug/L concentration. However, since the next highest test treatment is 50 ug/L, the NOEC will be 50 ug/L, and not the true no effect concentration of 90 ug/L.

In contrast, point estimates (e.g., the Effect Concentration (EC) and Inhibition Concentration (IC) point estimates) are empirically-derived estimates of the actual test concentration at which some magnitude of response occurs. For instance, the algal IC_{25} would be the test concentration at which there is expected to be a 25% reduction in algal cell density. The EC_{25} and IC_{25} can therefore be used to establish a regulatory limit based upon the degree of response that is determined to be acceptable by the regulatory agency.

2. The potential NOECs are limited to the test concentrations being tested. If the test concentrations are not specified, then the concentrations used in various studies may differ, hence resulting in different NOECs due strictly to lab practices.

In contrast, the EC and IC point estimates are independent of the test concentrations used.

3. The statistical methods for determining NOECs are limited to using only the data for the Control treatment and the test treatments in question. None of the other test data are used in that statistical comparison. As result, none of the other relevant test data information that help characterize concentration-response, etc., are being used.

In contrast, the calculation of the EC and IC point estimate use all of the test data to empirically model the concentration-response curve from which the point estimates are derived.

4. The statistical calculation of the NOEC is strongly determined by the inter-replicate variability that is achieved by the testing lab. Statistical power (i.e., the ability to detect "significant" differences between test treatments) is a direct function of inter-replicate variability: the lower the variability, the more powerful the statistics, and the greater ability to identify an increasingly smaller difference between treatments as being "significant". As a result, for a given test media, the NOEC could be expected to vary from lab to lab (or from test to test), depending upon each lab's ability to achieve precision in each test.

In contrast, the role of inter-replicate variability in concentration-response modeling is limited to the determination of the confidence limits - the determination of an EC or IC point estimate is relatively independent of inter-replicate variability.

The NOEC is a statistical benchmark that is easy to calculate and easy to understand, and it has a long history of regulatory usage for just these reasons. However, many scientists agree that there are serious problems with usage of NOECs in interpretation of toxicity tests (and therefore in the use of NOECs for criteria derivation), and that a regression-based approach such as used in the EC and IC point estimation approach is a better alternative. Indeed, regulatory programs that have conducted serious workshops and overhauls of their statistical methodologies have abandoned the NOEC and have adopted the regression-based approach (OECD 1998). Since the EC_{50} is available for the Blasburg et al., 1991 paper that the derivation authors are basing their proposed chronic criterion, this suggests that other point estimates would be available for the data. We encourage the authors consider using a more accurate point estimate for the diuron chronic criteria derivation rather than the NOEC.

We hope that our comments will prove helpful in improving the forthcoming revision of the Diuron Criteria Derivation so as to result in more scientifically defensible acute and chronic freshwater criteria for diuron.

Please feel free to contact us should you have any questions in regards to our comments.

Our regards,

Stephen L. Clark

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